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(54) **Prefill syringe**

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a prefill syringe wherein the syringe cartridge is prefilled with a drug and a rubber stopper is inserted into the cartridge to hermetically seal the drug therein.

Description of the Related Art

[0002] As the name implies, a prefill syringe is designed to reduce the time and trouble associated with the use of a syringe by providing a syringe which has been prefilled with a drug and completely sterilized prior to shipping by a pharmaceutical company. Thus, such a syringe can be used immediately. It is also known from document EP 568207 a syringe assembly having a cylindrical cartridge presenting a needle holder at one end and a collar at the other end thereof. The needle holder comprises a proximal luer hub and a needle affixed thereto.A cap for protecting the needle is attached to the needle holder, while a plunger stop is inserted into the cylindrical cartridge.
In one embodiement of the known syringe assembly, an eleastic cylindrical member is externally engaged to span the needle holder and the cap. The elastic cylindrical member presents a predeterminated number of ring-shaped projections, formed to an inner periphery, which contact an outer peripheral surface of the needle holder and an outer peripheral surface of the cap.
[0003] A prefill syringe of this design functions not only as a syringe, but also as a container for holding a drug over a long period of time. Accordingly, as in the case of a vial and ampoule, it is not only necessary to completely sterilize the container prior to filling with the drug, but it is also desirable to carry out a final sterilization of the prefilled syringe after it has been filled with the drug and sealed in order to complete sterilization during the production process.
[0004] However, as shown in Figure 13, in a prefill syringe 4 in which a syringe needle is attached to a needle holder 1 and a rubber stopper 2 is set inside a cartridge 3, ethylene oxide gas or vapor used in a gas or vapor sterilization treatment that is performed to the empty container before it is filled with a drug enters through opening 3a at the collar 5 end (i.e., the end opposite needle holder 1) of the prefill syringe, as indicated by the solid arrow lines in the figure. However, because the inside of cartridge 3 is sealed in an air and liquid tight fashion by the peaked, or outwardly projecting, portion, of rubber stopper 2, the flow of ethylene oxide gas toward needle holder 1 is blocked. As a result, the area from rubber stopper 2 to needle holder 1, or the area from rubber stopper 2 to the syringe needle portion, cannot be sterilized.

[0005] In order to resolve this problem, the area of joining between needle holder 1 of cartridge 3 and cap 6, or alternatively, the area of joining between the needle holder and a protector covering the syringe needle, is designed to permit the passage of gases from the external environment.
[0006] In other words, in the case of shipping syringes without attached syringe needles, a small interval of space is provided so that the area A of joining between cap 6 and needle holder I does not become airtightly sealed. Likewise, in the case of shipping syringes having an attached syringe needle, a small interval of space is provided so that the area A of joining between the syringe needle protector and the needle holder does not become airtightly sealed. Vapor or ethylene oxide gas enters into needle holder 1 through this interval of space as indicated by the dashed arrow lines in Figure 13. As a result, the area from rubber stopper 2 to needle holder 1 (or the syringe needle portion) can be sterilized.
[0007] Further, by providing the structure disclosed in "Package Sealing Portion for Sterilized Medical Devices" (Japanese Utility Model Laid Open Publication No. Hei 5-16657) to the inner side of a cap or protector, contamination from the plastic or through the space between the needle holder and a protector during the filling operation can be prevented. As a result, it is not necessary to again sterilize this area after filling.
[0008] Each part of cartridge 3 sterilized in this way prior to filling remains sterile after filling with the drug. Thus, post-filling sterilization is necessary only for those parts of cartridge 3 which come in contact with the drug, or for parts added or attached during the filling process. Other parts of cartridge 3 need not be sterilized again.
[0009] However, when the drug filling the cartridge is sterilized for a final time after filling by heating the cartridge with vapor or hot water from the outside, the vapor or hot water can enter the syringe via the space provided at joining area A between cap 6 and needle holder 1, or between the protector and needle holder 1. Thus, bacterial contamination can subsequently occur in any moisture which might remain inside the cartridge. Further, as in the case of drying an empty syringe prior to filling, the entire syringe (cartridge) containing the drug must be treated over a long period of time with high temperature dry air to remove this moisture through sufficient drying. Thus, depending on the type of drug being used in the syringe, the effect of this high temperature on the drug may be a cause for concern. For this reason, in order to carry out post-filling sterilization on a prefill syringe which has undergone sterilization prior to filling, it is necessary to employ some sort of method to cover the space at joining area A.
[0010] Moreover, it is necessary that the method for sealing this type of space be one which does not interrupt the flow of the filling process, employs an inexpensive material which is suitable for a disposable prefilled syringe, and is simple. These requirements have accordingly presented considerable obstacles to the real-

ization and wide-scale use of a prefill syringe.

SUMMARY OF THE INVENTION

[0011] The present invention was conceived in consideration of the aforementioned problems, and has as its objective the provision of a prefill syringe in which a space that is provided between the needle holder and a cap or protector for vapor or gas sterilization is covered by means of an inexpensive material and a simple method which do not interrupt the flow of the production process. As a result, the influx of vapor or hot water through the space at the area of joining between the needle holder and the cap or protector is prevented during a sterilization performed subsequent to drug filling.

[0012] The present invention is defined in claim 1.

[0013] The inner periphery of this cylindrical member may be provided with one or more ring-shaped projections which contact the outer peripheral surfaces of the needle holder and the cap.

[0014] This cylindrical member may be formed in the shape of a sheath having one end sealed and the other end open.

[0015] Further, a communicating hole which communicates the inside of the cylindrical member with the outside environment may be formed in the sealed end of the sheath-shaped cylindrical member.

[0016] A seal which engages in an air tight fashion about the circumference of the tip of the cap may be formed to the communicating hole formed at the sealed end of the sheath-shaped cylindrical member.

[0017] Further, this cylindrical member may be formed in the shape of a tube, with both ends open.

[0018] A syringe needle may be attached to the needle holder, and a protector which covers the syringe needle may be attached to the needle holder in place of a cap. A cylindrical member consisting of an elastic material is externally engaged to span between the needle holder and the protector so as to cover the area of joining between the needle holder and the protector. One or more ring-shaped projections which are in contact with the outer peripheral surfaces of the needle holder and the protector may be formed to the inner peripheral surface of the cylindrical member. Moreover, this cylindrical member is characterized in that one end is sealed while the other end is open.

[0019] A stepped portion may be provided at a point along the length of the outer periphery of the cylindrical member. The diameter at the tip of the cylindrical member, and the diameter extending between the outer edges of the stepped portion may differ.

[0020] In the present invention, a cylindrical member consisting of an elastic material is engaged externally to span between the needle holder and the cap so as to cover the area of joining therebetween. Thus, the space provided at the area of joining between the cap and the needle holder can be covered in an air and liquid tight fashion without interrupting the flow of the production process. As a result, the influx of vapor or hot water through the space at this area of joining during the sterilization process after the cartridge has been filled with the drug can be prevented.

[0021] Further, the syringes are packed without removing the elastic cylindrical member in a subsequent production step. Thus, the cylindrical member can be used as to augment grippability when removing the cap at time of use.

[0022] By forming one or more ring-shaped projections to the inner periphery of the cylindrical member which are in contact with the outer peripheral surfaces of the needle holder and the cap, the air and liquid tight seal between the cylindrical member and the needle holder or cap can be improved even further. Moreover, because there is little friction when inserting and disposing the cylindrical member, operability is improved.

[0023] By forming the cylindrical member in the shape of a sheath wherein one end is sealed and the other is open, errors in the direction of insertion of the cylindrical member are eliminated, since the end of the cylindrical member provided with the ring-shaped projections is always inserted first

[0024] By providing a communicating hole to the sealed end of a sheath-shaped cylindrical member for communicating the inside of the cylindrical member with the external environment, the exertion of an upward force on the cylindrical member due to the expansion of air remaining inside the cylindrical member as the temperature inside the cylindrical member increases during vapor sterilization does not occur. Thus, the cylindrical member does not shift in position, nor is there any deterioration in the quality of the seal between the cylindrical member and the needle holder.

[0025] Once the cylindrical member has been attached so as to cover the engagement between the cap and the needle holder, then even if a space arise between the outer sides of the cap and the inner peripheral surface of the cylindrical member due to the presence of vertical ribs formed to the outer periphery of the cap for example, it is possible to prevent vapor or the like from entering through this space during a vapor sterilization process carried out following drug filling.

[0026] By forming the cylindrical member in the shape of a tube with both ends open, the size of the cylindrical member can be minimized as necessary, thus reducing weight and cutting material costs.

[0027] By providing a stepped portion to the outer periphery of the cylindrical member, the stepped portion can be used for readily catching or moving the cylindrical member mechanically. Thus, the steps in the production process can be simplified. Further, when inserting the cylindrical member into the area of joining between the needle holder and the cap, or into the area of joining between the needle holder and the protector, the stepped portion can be employed as a measure of the degree of insertion of the cylindrical member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Fig. 1 shows the components of a prefill syringe according to the first embodiment of the present invention, where Fig. 1A shows the prefill syringe in vertical cross-section and Fig. 1B shows an enlargement of the area enclosed in the circle indicated by X in Fig. 1A.

[0029] Figure 2 is an enlarged cross-sectional diagram of the principle components of the cylindrical member according to the first embodiment.

[0030] Figure 3 is a diagram in vertical cross-section of the cylindrical member according to the second embodiment of the present invention.

[0031] Figure 4 is a diagram in vertical cross-section of the principle components of the prefill syringe according to the third embodiment of the present invention.

[0032] Figure 5 is a diagram in cross-section of the principle components of a prefill syringe according to the fourth embodiment of the present invention.

[0033] Figure 6 is a diagram in vertical cross-section of the principle components of a prefill syringe according to the fifth embodiment of the present invention.

[0034] Figure 7 shows a prefill syringe according to the sixth embodiment of the present invention, where Fig. 7A shows the prefill syringe in vertical cross-section and Fig. 7B shows the cylindrical member in cross-section.

[0035] Figure 8 shows a prefill syringe according to the seventh embodiment of the present invention, wherein the principle components of the prefill syringe are shown in vertical cross-section.

[0036] Figure 9 is a diagram shown in vertical cross-section of the cylindrical member according to the eighth embodiment of the present invention.

[0037] Figure 10 shows the prefill syringe according to the ninth embodiment of the present invention, wherein the principle components of the prefill syringe are shown in vertical cross-section.

[0038] Figure 11 shows the prefill syringe according to the tenth embodiment of the present invention, wherein the principle components are in cross-section to show the relationship between the cylindrical member and the cap.

[0039] Figure 12 shows the prefill syringe according to the eleventh embodiment of the present invention, wherein the components of the prefill syringe are shown in vertical cross-section.

[0040] Figure 13 is a cross-sectional diagram of the cartridge in a conventional prefill syringe.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0041] An explanation will now be made of each of the embodiments of the present invention, with reference being given to the figures.

<First Embodiment>

[0042] Figures 1 and 2 show a portion of the cartridge which composes a preloaded syringe according to the first embodiment of the present invention. Cartridge 10 is cylindrically shaped, with a needle holder 11 provided to one end and a collar provided to the other end thereof. Further, a rubber stopper 10a is inserted to be set inside cartridge 10. Note that Figure 1A shows only one end of cartridge 10, while the other end of the cartridge and the plunger rod or the like inserted in the cartridge are omitted.

[0043] A nozzle 12 and a collar 13 which is disposed external to and concentrically about nozzle 12 are provided to needle holder 11 of cartridge 10. A thread 13a is formed to the inner periphery of collar 13. As shown in Figure 5, a flange 14b formed to the needle base 14a of syringe needle 14 engages with this thread 13a during use.

[0044] A cap 15 is attached to needle holder 11 to maintain nozzle 12 in a sterile state. Cap 15 is provided with an attaching engagement 16 which overlaps the external periphery of nozzle 12 while still permitting the passage of gas, and a flange 17 which is provided projecting outward from attaching engagement 16. When flange 17 abuts the tip of collar 13 of needle holder 11, so that the outer peripheral surfaces of flange 17 and collar 13 lay in roughly the same plane, one or plural projections 17a which is provided protruding at the tip of flange 17 engages with an inner peripheral groove 13b at the end of collar 13. As a result cap 15 is engaged and fixed to needle holder 11.

[0045] A small space is formed at the joining area A between needle holder 11 and cap 15. A cylindrical member 20 is engaged externally to span needle holder 11 and cap 15 so as to cover joining area A where this space is provided.

[0046] Cylindrical member 20 is composed of a suitably elastic material such as rubber, and is formed in the shape of a tube which is open at both ends. As shown in Figure 2, a stepped portion 21 is formed at a point along the inner periphery of cylindrical member 20 in a shape which corresponds with the shape of cap 15. In Figure 2, the right side of the inner periphery of stepped portion 21 forms a large diameter portion 22, while the left side of the inner periphery of stepped portion 21 forms a small diameter portion 23. A plurality of ring-shaped projections 22a are formed at intervals to inner peripheral large diameter portion 22, with the spacing interval between ring-shaped projections 22a particularly wide at the center of inner peripheral large diameter portion 22. Ring-shaped projections 22a come in contact with the outer peripheral surfaces of needle holder 11 and cap 15, respectively, with each of these outer peripheral surfaces being in contact with at least one ring-shaped projection 22a respectively. In this embodiment, a total of 4 ring-shaped projections are formed, two contacting the outer peripheral surface of needle

holder 11 and two contacting the outer peripheral surface of cap 15.

[0047] The inner diameter of inner peripheral large diameter portion 22 of cylindrical member 20 is designed to be slightly larger than the outer diameters of needle holder 11 and cap 15. Moreover, the inner diameter of ring-shaped projections 22a inside inner peripheral large diameter portion 22 is designed to be slightly smaller than the outer diameters of needle holder 11 and cap 15.

[0048] The function of a prefilled syringe of the above described structure will now be explained.

[0049] In the actual drug filling process, as a general example, a prefill syringe in which a cap 15 is attached to a needle holder 11 undergoes a vapor or gas sterilization prior to filling with a drug. After sufficiently sterilizing the inside of needle holder 11, the prefill syringe is filled with a drug, and cylindrical member 20 is inserted over the tip of cap 15.

[0050] At this point, the entire inner peripheral surface of cylindrical member 20 does not adhere to the outer peripheral surfaces of cap 15 and needle holder 11. Rather, by means of the ring-shaped projections 22a alone, which are provided on the inner periphery of cylindrical member 20, the outer surfaces of both cap 15 and needle holder 11 are held tightly. Thus, friction upon insertion of the cylindrical member 20 is minimized, with the result that a smooth insertion can be accomplished mechanically without the intervention of human labor.

[0051] Cylindrical member 20 is inserted over the tip of cap 15. By inserting cylindrical member 20 to a position where a number of the ring-shaped projections 22a at the base end of the cap pass beyond the joining area A between needle holder 11 and cap 15, each of the ring-shaped projections 22a come in contact with either the outer periphery of cap 15 or the outer periphery of needle holder 11 so that cylindrical member 20 spans joining area A between cap 15 and needle hold 11. As a result the joining area A between cap 15 and needle holder 11 is completely sealed.

[0052] As a result, even if the prefill syringe is transferred to a vapor or hot water sterilization step after filling, the influx of vapor or hot water through the joining area A between cap 15 and needle holder 11 is prevented. Thus, it becomes possible to perform a sterilization process after the cartridge has been filled with the drug.

[0053] Further, by setting a cylindrical member 20 of this type on cap 15, cap 15 is provided with a outer diameter which is sufficiently large enough to permit easy grasping with the fingers even in the case where cartridge 10 itself has an extremely small diameter. As a result, cap 15 is easily removed at time of use, with cylindrical member 20 augmenting the ease of removal of the cap. Thus, the attachment of cylindrical member 20 to the cap after sterilization does not present a hindrance to shipment of the prefilled syringe. Accordingly, it is not necessary to provide a step to remove cylindrical member 20.

<Embodiment 2>

[0054] Figure 3 shows a second embodiment of the present invention. The same numerals have been employed here where components are identical to those in the first embodiment, and an explanation thereof has been omitted. This practice will be employed in the case of subsequent embodiments, as well.

[0055] The rubber cylindrical member 30 shown here is formed in the shape of a sheath, sealed at one end and open at the other. The length of cylindrical member 30 is such that the sealed end 30a of cylindrical member 30 does not interfere with the tip of cap 15 when it is set over the cap, thereby bringing the ring-shaped projections 22a provided to the inner periphery at the base end of the cylindrical member 30 into contact with the outer peripheral surfaces of the needle holder and the cap so that cylindrical member 30 spans the joining area between the needle holder and the cap.

[0056] As in the first embodiment, the entire inner surface of cylindrical member 30 does not adhere with the outer peripheral surfaces of cap 15 and needle holder 11 in this embodiment either. Rather, tight binding is accomplished by means of the ring-shaped projections 22a alone. As a result, cylindrical member 30 can be smoothly inserted mechanically over the cap, to prevent the influx of vapor or water droplets through the area of joining between the cap and the needle holder during a final sterilization process. Moreover, if cylindrical member 30 is grasped from above with the fingers when removing the cap, then, as was the case when employing a cylindrical member 20, cap 15 can be easily removed.

<Embodiment 3>

[0057] Figure 4 shows a third embodiment of the present invention.

[0058] As in the case of the cylindrical member 20 of the first embodiment, the cylindrical member 40 shown here is formed in the shape of a tube, open at both ends. However, this cylindrical member 40 is shorter than cylindrical member 20. Further, a plurality of ring-shaped projections are formed at intervals to the inner periphery of cylindrical member 40, as in the first and second embodiments.

[0059] By making cylindrical member 40 shorter, its insertion over the tip of cap 15 is facilitated in the case where cap 15 is comparatively long. Further, the material costs associated with cylindrical member 40 are reduced.

[0060] In other words, because both ends of cylindrical member 40 are open, when cylindrical member 40 is inserted over the tip of cap 15 for cartridge 10, such that a number of the ring shaped projections formed to the inner surface of cylindrical member 40 pass beyond the area of joining between needle holder 11 and cap 15, then the ring-shaped projections are in contact with the peripheral surfaces of cap 15 and needle holder 11

in the vicinity of the area of joining therebetween. Thus, needle holder 11 and cap 15 are tightly held, with ring-shaped projections 22a spanning the joining area A therebetween.

[0061] As in the first embodiment, the entire inner surface of the cylindrical member 40 does not adhere with the outer peripheral surfaces of cap 15 and needle holder 11. Rather, since the restraint is accomplished merely by means of ring-shaped projections 22a, cylindrical member 40 can be smoothly inserted mechanically. Further, an influx of water droplets through joining area A during a shower sterilization can be prevented. Moreover, at time of use of the prefill syringe, cap 15 can be removed easily by grasping cylindrical member 40 between the fingers and pulling it off, thereby pulling off the cap as well.

<Embodiment 4>

[0062] Figure 5 shows a fourth embodiment of the present invention.

[0063] In this fourth embodiment, a flange 14b formed to the needle base 14a screws together with a thread 13a on the inner periphery of collar 13, thereby attaching a syringe needle 14 to needle holder 11 prior to filling. In this embodiment, a protector 50 for protecting syringe needle 14 is employed in place of a cap. Protector 50 is attached to needle holder 11 such that an attaching engagement 51 at the base of protector 50 is joined to the outer periphery of needle base 14a under frictional force, while a flange 52 provided external to attaching engagement 51 lies opposite the tip of collar 13 of needle holder 11 with an interval of space present therebetween. In addition to joining the protector about the outer periphery of needle base 14a of syringe needle 14, other methods of attachment of protector 50 to needle holder 11 are available. For example, as in the first embodiment, one or plural projections provided at the tip of protector 50 may be engaged in inner periphery grooves 13b at the tip of collar 13.

[0064] A suitably elastic cylindrical member 55 is externally engaged to the area B of joining between needle holder 11 and protector 50, spanning it. Cylindrical member 55 is formed in the shape of a sheath with an inner diameter which is identical to or slightly larger than the outer diameters of collar 13 and protector 50 of needle holder 11. As in all of the preceding embodiments, a plurality of ring-shaped projections 22a are formed to the inner periphery of cylindrical member 55 with an interval of spacing therebetween. Further, when cylindrical member 55 is externally engaged to needle holder 11 and protector 50 so as to span the area of joining therebetween, ring-shaped projections 22a come in contact with the outer peripheral surfaces of needle holder 11 and protector 50 respectively, to seal joining area B.

[0065] In this prefill syringe, a prefill syringe with an attached syringe needle 14 undergoes vapor or gas sterilization prior to filling with a drug. Cartridge 10 is then filled with a drug, and cylindrical member 55 is inserted to a position where a number of the ring-shaped projections 22a formed to its inner periphery span the joining area B between needle holder 11 and protector 50, this operation being carried out without interruption to the production process.

[0066] As in the first embodiment, the entire surface of cylindrical member 55 does not adhere with the outer peripheral surfaces of protector 50 and needle holder 11. Rather, restraint is accomplished by means of the ring-shaped projections only, thus cylindrical member 55 can be smoothly inserted mechanically. Moreover, protector 50 can be easily removed together with cylindrical member 55 by grasping cylindrical member 55 between the fingers and pulling it off.

<Embodiment 5>

[0067] Figure 6 shows a fifth embodiment of the present invention.

[0068] In this embodiment, a cylindrical member 60 which is externally engaged to span across needle holder 11 and protector 50 so as to cover the joining area B therebetween is formed in the shape of a tube, with both ends open, rather than in the shape of a sheath as in the fourth embodiment shown in Figure 5.

[0069] In this embodiment, the preloaded syringe with attached syringe needle 14 undergoes a gas or vapor sterilization prior to filling with the drug. The cartridge is then filled with the drug, and cylindrical member 60 is inserted to a position where it covers the joining area B between needle holder 11 and protector 50. These operations are carried out mechanically in a smooth fashion, without interruption to the production process.

<Embodiment 6>

[0070] Figure 7 shows a sixth embodiment of the present invention.

[0071] In this embodiment, cylindrical member 70 which engages to span between needle holder 11 and cap 15 is formed in shape of a sheath, with one end sealed and the other open.

[0072] Further, a communicating hole 71 is formed in the approximate center of the closed end of cylindrical member 70 for communicating the inside of cylindrical member 70 with the outside environment.

[0073] In this embodiment, as in the previous embodiments, ring-shaped projections 22a formed to the inside of cylindrical member 70 adhere to the outer peripheral surfaces of cap 15 and needle holder 11. As a result, the influx of water droplets or the like through joining area A during a shower sterilization can be prevented with certainty. Moreover, cap 15 can be removed easily at time of use by gripping cylindrical member 70 between the fingers and removing it along with cap 15.

[0074] Further, in this embodiment, the area inside cy-

lindrical member 70, namely the space 72 enclosed by the inner peripheral surface of cylindrical member 70 and the outer peripheral surface of the cap, is open to the external environment via communicating hole 71. Thus, even when the temperature inside cylindrical member 70 increases during a vapor sterilization, there is no upward force applied on cylindrical member 70 by expanding air since air does not remain inside space 72. Thus, there is no concern that the seal between cylindrical member 70 and needle holder 11 and the like will deteriorate due to a shift in the position of cylindrical member 70 caused by increasing pressure from expanding air.

<Embodiment 7>

[0075] Figure 8 shows a seventh embodiment of the present invention.

[0076] In this embodiment, a cylindrical member 80 is externally engaged to span the joining area B between needle holder 11 and protector 50. As in the previous embodiments, a plurality of ring-shaped projections are formed to the inner periphery of cylindrical member 80 with an interval of spacing therebetween. Further, a communicating hole 81 which communicates the inside of cylindrical member 80 with the outside environment is formed at the approximate center of the sealed end of cylindrical member 80.

[0077] As in embodiment 6, in this embodiment the ring-shaped projections formed to the inside of the cylindrical member 80 adhere to the outer peripheral surfaces of cap 15 and needle holder 11. Thus, the influx of water droplets through joining area B between needle holder 11 and protector 50 is prevented with certainty. Moreover, even when the temperature inside cylindrical member 80 increases during a vapor sterilization, there is no upward force applied on cylindrical member 80 by expanding air remaining inside the member. Thus, there is no concern that the seal between cylindrical member 80 and needle holder 11 and the like will deteriorate due to a shift in the position of cylindrical member 80.

<Embodiment 8>

[0078] Figure 9 shows an eighth embodiment of the present invention.

[0079] In this embodiment, a stepped portion 91 is formed midway along the length of the outer periphery of a rubber cylindrical member 90 which may be formed in the shape of the sheath or tube explained in the first through seventh embodiments above (Figure 9 shows the case where cylindrical member 90 is formed in the shape of a sheath). The diameter D1 at the tip of cylindrical member 90, and the diameter D2 which extends between the outer edges of stepped portion 91 differ, with diameter D2 being larger than diameter D1.

[0080] Additionally, the provision of a plurality of ring-shaped projections 22a formed to the inner periphery of cylindrical member 90 with spacing therebetween is identical to that in the previous embodiments.

[0081] In this design wherein a stepped portion 91 is provided to the outer periphery of cylindrical member 90, stepped portion 91 can be employed to permit ready catching or transfer of cylindrical member 90 mechanically. As a result, the production process can be simplified. Further, when cylindrical member 90 is inserted into the area of joining between the needle holder and the cap, or the area of joining between the needle holder and a protector, stepped portion 91 can be employed as a standard to judge the extent of insertion of cylindrical member 90.

<Embodiment 9>

[0082] Figure 10 shows a ninth embodiment of the present invention.

[0083] In this embodiment, a seal 102 is provided to communicating hole 71 formed at the sealed end of the cylindrical member 70 of the sixth embodiment shown in Figure 7. Seal 102 engages with the circumferential portion 100 at the tip of cap 15 in an airtight fashion.

[0084] Taking into consideration interference, the inner diameter of communicating hole 71 of cylindrical member 70 prior to attachment is identical to or slightly smaller than the outer diameter of circumferential portion 100 at the tip of cap 15. Seal 102 is composed of the entire area of the inner periphery of communicating hole 71.

[0085] In other words, a plurality of vertical ribs 104,... which project outward are formed to the external periphery of cap 15 about the circumference thereof. However, these vertical ribs 104,.. are not formed to extend to the tip of cap 15. Rather, the tip of cap 15 is formed in a simple circular shape. In the embodiment shown here, the inner peripheral surface of communicating hole 71 is pressed against the outer periphery of this simple circular portion, to form the seal between cap 15 and cylindrical member 70.

[0086] The design of this embodiment compensates for the drawbacks present in the sixth embodiment of the present invention shown in Figure 7.

[0087] In other words, in the present invention's sixth embodiment in Figure 7, the space 72 enclosed by the inner peripheral surface of cylindrical member 70 and the outer peripheral surface of cap 15 is open to the outside via communicating hole 71. As a result, air does not become trapped in space 72, making it possible to prevent the exertion of an upward force on cylindrical member 70 due to expansion of air trapped in space 72 when the temperature rises during a sterilization process or the like. However, in this case, the following disadvantages could arise. Namely, the inner peripheral surface of cap 15 is lifted outward by vertical ribs 104,.. formed to the outer sides of cap 15. As a result, a space occurs between the outer sides of cap 15 and the inner peripheral surface of cylindrical member 70, causing

loss of the airtight seal. Then, during vapor sterilization following filling with the drug, vapor or hot water could enter via communicating hole 71 and the space between the outer sides of cap 15 and the inner peripheral surface of cylindrical member 70, reaching joining area A between needle holder 11 and cap 15 and entering into needle holder 11.

[0088] However, in this ninth embodiment, in addition to providing a communicating hole 71 to communicate the space 72 enclosed between the inner peripheral surface of cylindrical member 70 and the outer peripheral surface of cap 15 with the external environment, a seal 102 which engages in an airtight manner with the circumferential portion 100 at the tip of cap 15 is provided to communicating hole 71. Accordingly, after cylindrical member 70 has been attached so as to cover the area of engagement between cap 15 and needle holder 11, the influx of vapor or hot water from the outside via a space which may arise between the outer sides of cap 15 and the inner peripheral surface of cylindrical member 70 due to vertical ribs 104,... is prevented. In other words, the design of this embodiment makes it possible to eliminate air remaining inside space 72, while preventing the influx of vapor from the outside.

[0089] Additionally, a stepped portion 91 has been provided to the outer periphery of cylindrical member 70.

<Embodiment 10>

[0090] Figure 11 shows a tenth embodiment of the present invention.

[0091] In this embodiment, the provision of a seal 102 to communicating hole 71 formed at the sealed end of a sheath-shaped cylindrical member 70 is identical to embodiment 9. However, the substantial difference in this embodiment is that seal 102 is formed of a ring-shaped projection 110 that is formed to the inner peripheral surface of communicating hole 71.

[0092] As in the previous embodiment, in this embodiment as well, once cylindrical member 70 has been attached so as to cover the area of engagement between cap 15 and needle holder 11, the influx of vapor or hot water during vapor sterilization from the outside via a space which may arise between the outer sides of cap 15 and the inner peripheral surface of cylindrical member 70 due to vertical ribs 104,... is prevented.

[0093] In the ninth embodiment shown in Figure 10, the seal is composed of the entire area of the inner peripheral surface of communicating hole 71. For this reason, the dimensions of the inner diameter of communicating hole 71 and the outer diameter of the circumferential portion 100 at the tip of cap must be carefully controlled in order to ensure an excellent airtight seal therebetween. However, in the tenth embodiment shown here, seal 102 is formed by a ring shaped projection 110 which permits a wide range of permissible variations in form. Thus, in this embodiment, strict regulation of the relationship between the dimensions of the inner diameter of communicating hole 71 and the outer diameter of the circumferential portion of the tip of cap 15 is not necessary; rather comparatively loose control of these dimensions is sufficient.

<Embodiment 11>

[0094] Figure 12 shows an eleventh embodiment of the present invention.

[0095] In this embodiment, a seal 122 which engages in an airtight fashion with the circumferential portion 120 at the tip of protector 50 is provided to communicating hole 81 which is formed in the closed end of the sheath-shaped cylindrical member 80 of the seventh embodiment shown in Figure 8.

[0096] As in the ninth embodiment, seal 122 is composed of the entire area of the inner periphery of communicating hole 81.

[0097] In this embodiment, as in the ninth embodiment, after cylindrical member 80 has been attached so as to cover the area of engagement between protector 50 and needle holder 11, the influx of vapor or hot water from the outside via a space which may arise between the outer sides of protector 50 and the inner peripheral surface of cylindrical member 80 due to vertical ribs 124,.. formed to the outer surface of protector 50 is prevented. In other words, the design of this embodiment makes it possible to eliminate air remaining inside cylindrical member 80, while preventing the influx of vapor from the outside.

[0098] In the preceding embodiments, ring-shaped projections 22a were formed to the inner periphery of an elastic cylindrical member. These ring-shaped projections 22a are not absolutely necessary, however.

[0099] Further, the above embodiments described the case where 4 ring-shaped projections are provided, however, this is not a strict limitation but rather 6 or 8 ring-shaped projections may be provided.

[0100] Moreover, in the preceding embodiments, ring-shaped projection 22a was formed to be a semisphere in cross-section. However, the shape of ring-shaped projection 22a is not limited to this, but may form a square, triangle or half-ellipse in cross-section.

Claims

1. A prefill syringe provided with:

   - a cylindrical cartridge (10) having a needle holder (11) at one end and a collar (5) at the other end thereof, said needle holder (11) defining an inside cavity being capable of receiving a needle (14), said base of a needle inside cavity of the needle holder (11) being so shaped as to be suitable of being placed in fluid communication with an inside cavity of said needle (14);

- a plunger rod to be inserted in the cylindrical cartridge (10);
- a rubber stopper (10a) to be inserted in the cylindrical cartridge (10);
- a cap (15) for protecting the needle holder (11) and attached to the needle holder (11), said cap (15) and said needle holder (11) defining, in an assembled condition, a space therebetween, said space being both in fluid communication with the inside cavity of the needle holder (11) and being so shaped as to be suitable of being placed in fluid communication with the external environment;
- an elastic cylindrical member (20) externally engaged to span the needle holder (11) and the cap (15), said elastic cylindrical member (20) being shiftable from a non-operating position where it is dislocated from the space so as to allow communication between the inside cavity of the needle holder (11) and the external environment via the space for enabling vapor or gas to enter the needle holder (11) during gas sterilization performed prior to filling the syringe with drug, and an operating position in which the elastic cylindrical member (20) acts in closure of the space preventing influx of vapor or hot water during a sterilization performed subsequent to drug filling.

2. A prefill syringe according to claim 1, **characterized in that** said cylindrical member (20) presents one or more ring-shaped projections (22a), formed to an inner periphery, which contact an outer peripheral surface of the needle holder (11) and an outer peripheral surface of the cap (15) for minimizing friction upon insertion of the cylindrical member (20) on the cap (15).

3. A prefill syringe according to claims 1 or 2, **characterized in that** the needle holder (11) comprises at least one inner periphery groove (13b) and **in that** the cap (15) comprises at least a projection (17a), the cap (15) being directly attached to the needle holder (11) via relative engagement of said projection (17a) to said inner periphery groove (13b).

4. A prefill syringe according to claim 1, wherein the cylindrical member (30) is formed in shape of a sheath in which one end is sealed and the other end is open.

5. A prefill syringe according to claim 4, wherein a communicating hole (71) which communicates inside of the cylindrical member with the external environment is formed in the sealed end of the sheath-shaped cylindrical member (70).

6. A prefill syringe according to claim 5, wherein a seal (102) which engages in an airtight fashion with a circumferential portion (100) at the tip of the cap (15) is provided around a communicating hole formed in the end of the sheath-shaped cylindrical member (70) being opposite the needle holder (11).

7. A prefill syringe according to claim 1, wherein the cylindrical member (20,40) is formed in the shape of a tube in which both ends are open.

8. A prefill syringe according to claim 4, wherein a syringe needle (14) is attached to the needle holder (11) and the cap has the form of the protector (50) attached to the needle holder (11) so as to cover the syringe needle (14), the elastic cylindrical member (55) being externally engaged to span across the needle holder (11) and the protector (50) so as to cover the joining area (B) therebetween, one or more ring-shaped projections (22a) which contact the outer peripheral surface of the needle holder and the outer peripheral surface of the protector are formed to the inner periphery of the cylindrical member, and the cylindrical member is formed in the shape of a sheath in which one end is open and the other end is sealed.

9. A prefill syringe according to claim 8 wherein a communicating hole (81) which communicates inside of the cylindrical member with the external environment is formed in the sealed end of the sheath-shaped cylindrical member (80).

10. A prefill syringe according to claim 8, wherein the cylindrical member (60) is formed in the shape of a tube which is open at both ends.

11. A prefill syringe according to anyone of the preceding claims from 1 to 10, wherein a stepped portion (91) is provided at a point along the length of the cylindrical member (90) to an outer periphery thereof, a diameter (D1) at the tip of the cylindrical member being different than a diameter (D2) extending across outer edges of the stepped portion.

Patentansprüche

1. Vorfüllspritze, mit:

   - einer zylindrischen Patrone (10), welche einen Nadelhalter (11) an einem Ende und einen Kragen (5) an ihrem anderen Ende aufweist, wobei der Nadelhalter (11) eine Innenausnehmung festlegt, die in der Lage ist, eine Nadelbasis einer Nadel (14) aufzunehmen, wobei die innere Ausnehmung des Nadelhalters (11) so geformt ist, daß sie geeignet ist, in Fluidverbindung mit einer inneren Ausnehmung der Nadel (14) ge-

bracht zu werden;

- einem Kolbenstab, der in die zylindrische Patrone (10) eingeführt ist,
- einem Gummistöpsel (10a), der in die zylindrische Patrone (10) eingeführt ist,
- einer Kappe (15), um den Nadelhalter (11) zu schützen und am Nadelhalter (11) angebracht ist, wobei die Kappe (15) und der Nadelhalter (11) im zusammengebauten Zustand einen Raum dazwischen bilden, wobei der Raum sowohl in Fluidverbindung mit der inneren Ausnehmung des Nadelhalters (11) steht als auch so geformt ist, daß er geeignet ist, in Fluidverbindung mit der äußeren Umgebung gebracht zu werden;
- einem elastischen zylindrischen Teil (20), welches extern erfaßt wird, um den Nadelhalter (11) und die Kappe (15) zu überspannen, wobei das elastische zylindrische Teil (20) von einer Nichtbetriebsposition, wo es vom Raum gelöst ist, um eine Verbindung zwischen der inneren Ausnehmung des Nadelhalters (11) und der externen Umgebung über den Raum zu erlauben, um so zu ermöglichen, daß Dampf oder Gas in den Nadelhalter (11) während einer Gassterilisierung eintreten, die vor dem Füllen der Spritze mit dem Medikament durchgeführt wird, und einer Betriebsposition verschiebbar ist, bei der das elastische zylindrische Teil (20) als Verschluß des Raums wirkt, um das Eindringen von Dampf oder heißem Wasser während einer Sterilisierung, die im Anschluß an das Medikamentenfüllen durchgeführt wird, zu verhindern.

2. Vorfüllspritze nach Anspruch 1, **dadurch gekennzeichnet, daß** das zylindrische Teil (20) einen oder mehrere ringförmige Ansätze (22a) aufweist, die auf einem inneren Umfang gebildet sind, welche eine äußere Umfangsfläche des Nadelhalters (11) und eine äußere Umfangsfläche der Kappe (15) kontaktieren, um die Reibung beim Aufsetzen des zylindrischen Teils (20) auf die Kappe (15) zu minimieren.

3. Vorfüllspritze nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** der Nadelhalter (11) zumindest eine innere Umfangsnut (13b) aufweist, und daß die Kappe (15) zumindest einen Ansatz (17a) aufweist, wobei die Kappe (15) unmittelbar am Nadelhalter (11) über einen gegenseitigen Eingriff des Ansatzes (17a) mit der inneren Umfangsnut (13b) angebracht ist.

4. Vorfüllspritze nach Anspruch 1, wobei das zylindrische Teil (30) die Form einer Hülle aufweist, bei der ein Ende abgedichtet ist und das andere Ende offen ist.

5. Vorfüllspritze nach Anspruch 4, wobei ein Verbindungsloch (71), welches die Innenseite des zylindrischen Teils mit der äußeren Umgebung verbindet, im abgedichteten Ende des hüllenförmigen zylindrischen Teils (70) gebildet ist.

6. Vorfüllspritze nach Anspruch 5, wobei eine Abdichtung (102), welche in luftdichter Weise ein Umfangsteil (100) an der Spitze der Kappe (15) erfaßt, um ein Verbindungsloch herum vorgesehen ist, welches im Ende des hüllenförmigen zylindrischen Teils (70) gebildet ist, welches gegenüber dem Nadelhalter (11) ist.

7. Vorfüllspritze nach Anspruch 1, wobei das zylindrische Teil (20, 40) in Form einer Röhre gebildet ist, bei der beide Enden offen sind.

8. Vorfüllspritze nach Anspruch 4, wobei eine Spritzennadel (14) am Nadelhalter (11) angebracht ist und die Kappe die Form des Schutzteils (50) aufweist, welches am Nadelhalter (11) angebracht ist, um die Spritzennadel (14) zu überdecken, wobei das elastische zylindrische Teil (55) extern erfaßt wird, um sich über den Nadelhalter (11) und das Schutzteil (50) zu spannen, um den Verbindungsbereich (B) dazwischen zu überdecken, ein oder mehrere ringsförmige Ansätze (22a), welche die äußere Umfangsfläche des Nadelhalters und die äußere Umfangsfläche des Schutzteils kontaktieren, am inneren Umfang des zylindrischen Teils gebildet sind, und das zylindrische Teil in Form einer Hülle ausgebildet ist, bei der ein Ende offen ist und bei das andere Ende abgedichtet ist.

9. Vorfüllspritze nach Anspruch 8, wobei ein Verbindungsloch (81), welches die Innenseite des zylindrischen Teils mit der äußeren Umgebung verbindet, im abgedichteten Ende des hüllenförmigen zylindrischen Teils (80) gebildet ist.

10. Vorfüllspritze nach Anspruch 8, wobei das zylindrische Teil (60) in Form einer Röhre gebildet ist, die an beiden Enden offen ist.

11. Vorfüllspritze nach einem der vorhergehenden Ansprüche 1 bis 10, wobei ein abgesetzter Bereich (91) an einem Punkt längs der Länge des zylindrischen Teils (90) zu dessen äußerem Unfang vorgesehen ist, wobei ein Durchmesser (D1) an der Spitze des zylindrischen Teils anders ist als ein Durchmesser (D2), der sich über äußere Ränder des abgesetzten Teils erstreckt.

Revendications

1. Seringue préremplie, comportant :

- une cartouche cylindrique (10) munie d'un support d'aiguille (11) à une extrémité et d'un collier (5) à son autre extrémité, ledit support d'aiguille (11) délimitant une cavité interne capable de recevoir une base d'aiguille d'une aiguille (14), ladite cavité interne du support d'aiguille (11) étant conformée de façon adaptée pour être placée en communication de fluide avec une cavité interne de ladite aiguille (14) ;
- une tige de plongeur devant être insérée dans la cartouche cylindrique (10) ;
- un bouchon en caoutchouc (10a) devant être inséré dans la cartouche cylindrique (10) ;
- un capuchon (15) pour protéger le support d'aiguille (11) et attaché au support d'aiguille (11), ledit capuchon (15) et ledit support d'aiguille (11) délimitant, à l'état assemblé, un espace entre eux, ledit espace étant à la fois en communication de fluide avec la cavité interne du support d'aiguille (11) et étant profilé de façon adaptée pour être mis en communication de fluide avec l'environnement externe ;
- un organe cylindrique élastique (20) engagé extérieurement pour couvrir le support d'aiguille (11) et le capuchon (15), ledit organe cylindrique élastique (20) pouvant être déplacé depuis une position non opératoire dans laquelle il est disjoint de l'espace, de façon à autoriser une communication entre la cavité interne du support d'aiguille (11) et l'environnement externe via l'espace pour permettre à de la vapeur ou à du gaz de pénétrer dans le support d'aiguille (11) durant une stérilisation gazeuse exécutée avant le remplissage de la seringue par un médicament, et une position opératoire dans laquelle l'organe cylindrique élastique (20) agit par obturation de l'espace, empêchant l'introduction de vapeur ou d'eau chaude durant une stérilisation exécutée après un remplissage de médicament.

2. Seringue préremplie selon la revendication 1, **caractérisée en ce que** l'organe cylindrique (20) présente une ou plusieurs parties saillantes (22a) en forme de bagues, formées sur une périphérie intérieure, qui viennent en contact avec une surface périphérique externe du support d'aiguille (11) et une surface périphérique externe du capuchon (15) pour minimiser le frottement lors de l'insertion de l'organe cylindrique (20) sur le capuchon (15).

3. Seringue préremplie selon la revendication 1 ou 2, **caractérisée en ce que** le support d'aiguille (11) comprend au moins une rainure périphérique intérieure (13b), et **en ce que** le capuchon (15) comporte au moins une partie saillante (17a), le capuchon (15) étant directement attaché au support d'aiguille (11) via un engagement de ladite partie saillante (17a) par rapport à ladite rainure périphérique intérieure (13b).

4. Seringue préremplie selon la revendication 1, **caractérisée en ce que** l'organe cylindrique (30) est réalisé sous la forme d'un étui dont une extrémité est étanche et l'autre est ouverte.

5. Seringue préremplie selon la revendication 4, **caractérisée en ce qu'**un trou de communication (71), qui met en communication l'intérieur de l'organe cylindrique avec l'environnement externe, est formé dans l'extrémité étanche de l'organe cylindrique (70) conformé en étui.

6. Seringue préremplie selon la revendication 5, **caractérisée en ce qu'**un joint d'étanchéité (102) qui coopère de manière étanche à l'air avec une partie circonférentielle (100) à la pointe du capuchon (15), est agencé autour d'un trou de communication formé dans l'extrémité de l'organe cylindrique (70) conformé en étui, à l'opposé du support d'aiguille (11).

7. Seringue préremplie selon la revendication 1, **caractérisée en ce que** l'organe cylindrique (20, 40) est agencé sous la forme d'un tube dont les deux extrémités sont ouvertes.

8. Seringue préremplie selon la revendication 4, **caractérisée en ce qu'**une aiguille (14) de seringue est attachée au support d'aiguille (11) et **en ce que** le capuchon présente la forme du protecteur (50) attaché au support d'aiguille (11) de façon à recouvrir l'aiguille (14) de la seringue, l'organe cylindrique élastique (55) étant extérieurement engagé pour s'étendre sur le support d'aiguille (11) et le protecteur (50) de façon à couvrir la zone (B) de jonction entre eux, **en ce qu'**une ou plus d'une parties saillantes (22a) conformées en bagues qui viennent au contact de la surface périphérique extérieure du support d'aiguille et de la surface périphérique extérieure du protecteur sont formées à la périphérie intérieure de l'organe cylindrique, et l'organe cylindrique est réalisé sous la forme d'un étui dans lequel une extrémité est ouverte et l'autre extrémité est étanche.

9. Seringue préremplie selon la revendication 8, **caractérisée en ce qu'**un trou (81) de communication qui met en communication l'intérieur de l'organe cylindrique avec l'environnement externe est formé dans l'extrémité étanche de l'organe cylindrique (80) conformé en étui.

10. Seringue préremplie selon la revendication 8, **caractérisée en ce que** l'organe cylindrique (60) est réalisé sous la forme d'un tube ouvert à ses deux

extrémités.

11. Seringue préremplie selon l'une quelconque des revendications1 à 10, **caractérisée en ce qu'**une partie en gradin (91) est prévue à un emplacement suivant le long de l'organe cylindrique (90) jusqu'à une périphérie extérieure de celui-ci, un diamètre (D1) à la pointe de l'organe cylindrique étant différent d'un diamètre (D2) qui s'étend transversalement aux bords extérieurs de la partie en gradin.

FIG.1A

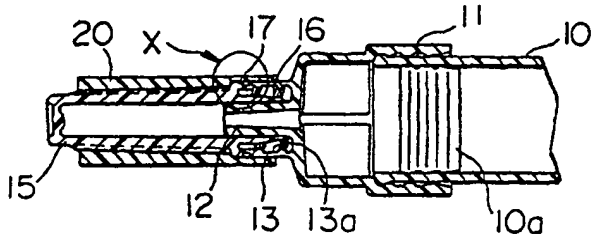

FIG.1B

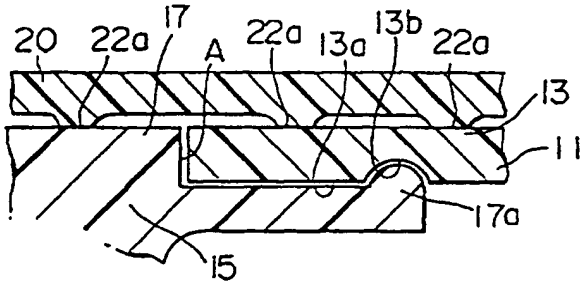

FIG.2

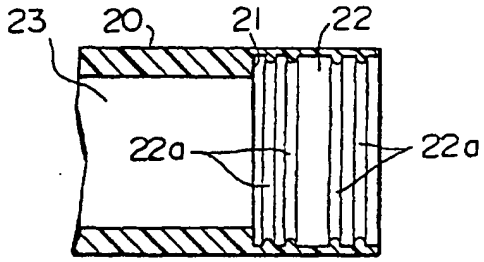

FIG.3

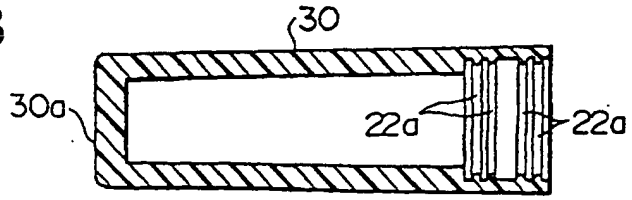

FIG.4

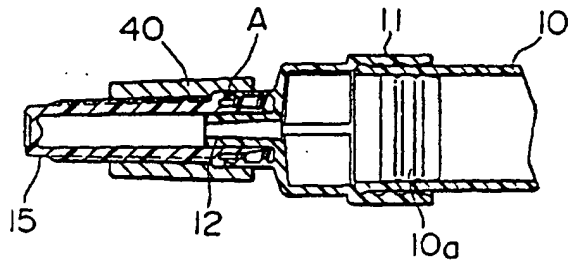

FIG.5

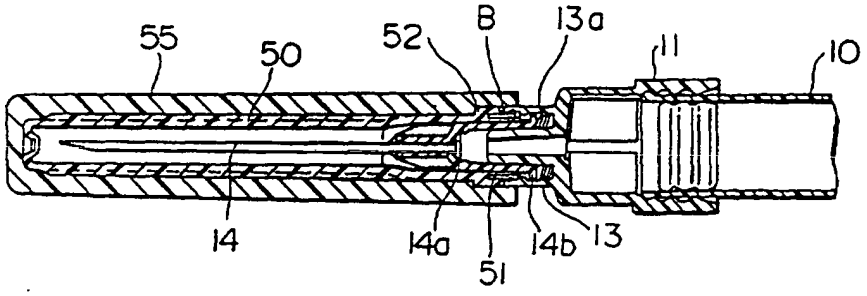

FIG.6

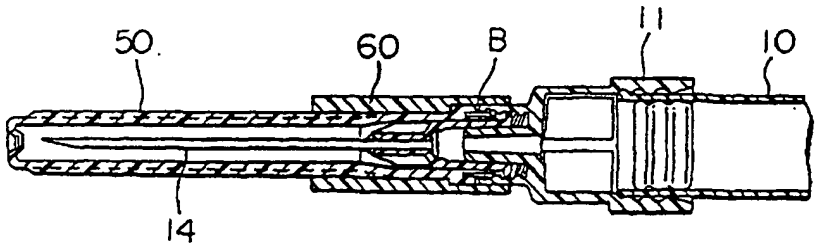

FIG.7A

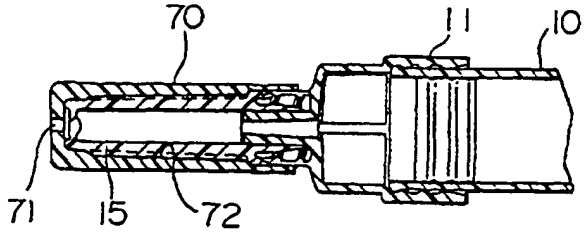

FIG.7B

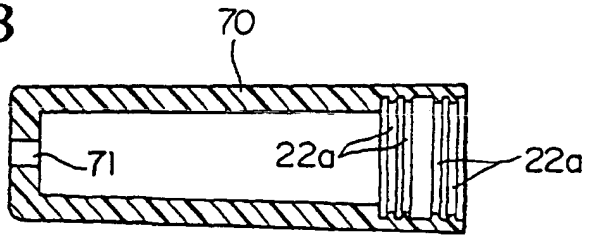

FIG.8

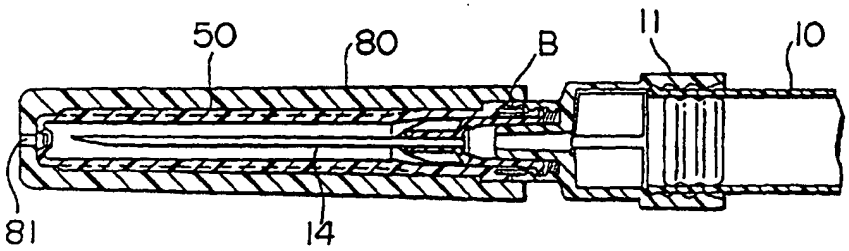

FIG.9

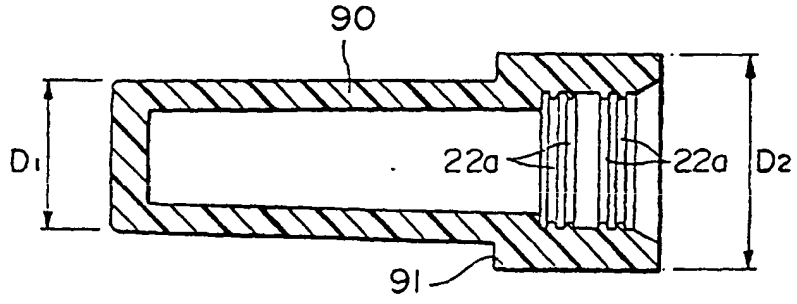

FIG.10

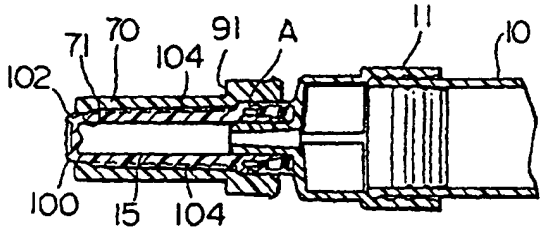

FIG.11

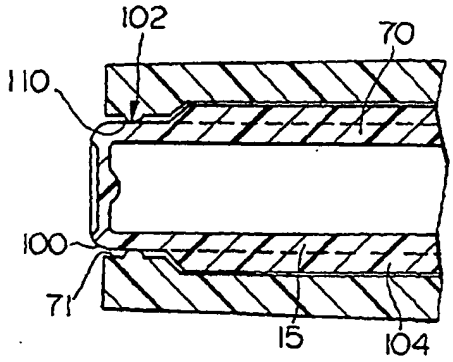

FIG.12

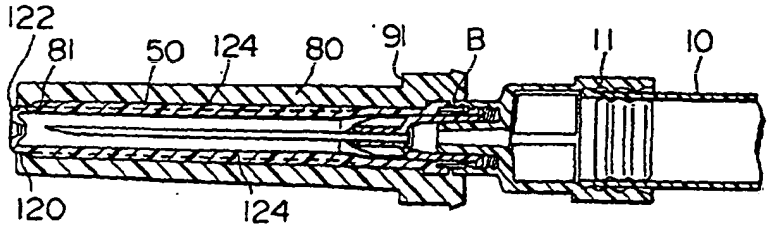

FIG.13